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# Self-medication of regular headache: a community pharmacy-based survey

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## ABSTRACT

**Background:** This observational community pharmacy-based study aimed to investigate headache characteristics and medication use of persons with regular headache presenting for self-medication.

**Methods:** Participants (n=1205) completed (i) a questionnaire to assess current headache medication and previous physician diagnosis, (ii) the ID Migraine Screener (ID-M) and (iii) the MIDAS questionnaire.

**Results:** Forty-four % of the study population (n=528) did not have a physician diagnosis of their headache, and 225 of them (225/528, 42.6%) were found to be ID-M positive. The most commonly used acute headache drugs were paracetamol (used by 62% of the study population), NSAIDs (39%) and combination analgesics (36%). Only 12% of patients physician-diagnosed with migraine used prophylactic migraine medication, and 25% used triptans. About 24% of our sample (n=292) chronically overused acute medication, which was combination analgesic overuse (n=166), simple analgesic overuse (n=130), triptan overuse (n=19), ergot overuse (n=6) and opioid overuse (n=5). Only 14.5% was ever advised to limit intake frequency of acute headache treatments.

**Conclusions:** This study identified underdiagnosis of migraine, low use of migraine prophylaxis and triptans, and high prevalence of medication overuse among subjects seeking self-medication for regular headache. Community pharmacists have a strategic position in education and referral of these self-medicating headache patients.

## INTRODUCTION

Headache is a common reason for self-treatment with over-the-counter (OTC) medication. However, overuse of acute headache medication through inappropriate self-medication can cause medication-overuse headache (MOH). Medication-overuse and subsequent MOH is an increasing problem worldwide. Epidemiological data suggest that the prevalence of MOH is at least 1% of adults in the general population, and up to 30-50% in patients attending tertiary headache centers (1, 2). Diagnosis is not always evident, especially because patients often self-treat without consulting a physician.

Community pharmacists could play an important role in early detection and prevention of MOH, by monitoring self-medication of headache and educating patients about the maximum intake frequency of acute treatments. Before effective pharmacy programs can be designed, observational data on the headache characteristics and the drug utilization of individuals seeking self-medication for headache are required. To date, literature on this topic is scarce. We found only one paper, describing a small observational study (22 participants) that assessed the degree of headache-related disability and treatment views of persons purchasing OTC headache products at community pharmacies (3). The other pharmacy-based studies published so far did not focus on self-medicating customers, but were: a descriptive study on headaches, drug consumption and life habits of migraine patients (4), the development and validation of a pharmacy migraine questionnaire to assess eligibility for triptan use (5), and an intervention trial evaluating the effects of pharmaceutical care for migraine and headache patients (6).

The present observational community pharmacy-based study aimed to investigate the headache characteristics and the medication use of persons with regular headache, defined for this study as headache occurring at least once per month, presenting for self-medication. These data should allow us to formulate recommendations for improved primary care management of headache. The work was reported in preliminary form at the 15<sup>th</sup> European Federation of Neurological Societies (EFNS) Congress, Budapest, September 2011.

## METHODS

### **Study design**

This observational study was carried out from December 2009 till May 2010 in 152 randomly selected community pharmacies in Belgium. Approval for the study was granted by the Ethics Committees of Ghent University Hospital (for Flanders) and CHU Liege (for Wallonia), and all patients gave written informed consent.

### **Participants**

Pharmacy customers purchasing an OTC analgesic (OTC analgesics available in Belgium: paracetamol, acetylsalicylic acid, ibuprofen 200-400 mg, naproxen 200 mg, and caffeine-containing combination analgesics) were approached consecutively and asked whether they bought the OTC analgesic for headache. In case of a positive answer, they were invited to participate in the study when fulfilling the following inclusion criteria: being aged  $\geq 18$  years, purchasing the headache medication for themselves, and suffering from headache  $\geq 1$ x/month. From each of the pharmacies, ten patients were planned to be recruited.

### **Data collection**

Persons who agreed to participate filled out a self-administered questionnaire, collecting the following information: age, gender, physician diagnosis of headache (if available), current acute and preventive headache medication (prescription and non-prescription) with frequency of use during the prior 3 months, and whether they were ever advised to limit intake of acute headache medication. A medication overuser was defined as a person overusing acute headache medication in terms of treatment days per month ( $\geq 10$  days/month for ergotamine, triptans, opioids, and combination analgesics;  $\geq 15$  days/month for paracetamol, ASA, and NSAIDs) during the previous 3 months, according to the revised criteria of the International Classification of Headache Disorders Second Edition (ICHD-II) for MOH (7).

All participants also completed the ID Migraine Screener (ID-M), a valid and reliable screening instrument for migraine in primary care (8), and the Migraine Disability Assessment (MIDAS) questionnaire (9-11). The MIDAS consists of five scored questions on headache-related disability and two additional unscored questions on headache frequency (“On how many days in the last 3 months did you have any headache [if a headache lasted more than 1 day, count each day]?”) and pain intensity (“On a scale from 0 to 10, on average how painful were these headaches?”, where 0 = no pain at all, and 10 = pain as bad as it can be). The MIDAS score is classified into four grades of severity: little or no disability (grade I, MIDAS score 0-5), mildly limiting disability (grade II, MIDAS score 6-10), moderately limiting disability (grade III, MIDAS score 11-20), and severely limiting disability (grade IV, MIDAS score >20).

### **Data analysis**

Statistical data analysis was performed using SPSS 17.0 for Windows (SPSS Inc, Chicago, IL, USA). First, headache characteristics and medication use were described for the entire study population. Second, extra analyses were performed on a specific subgroup of interest, i.e. medication overusers. To compare subgroup results, we used Pearson’s chi square tests (for categorical data) and Mann-Whitney U tests (for ordinal data [MIDAS grade, pain intensity] and for non-normally distributed continuous data [headache frequency]). P-values of <0.05 were considered significant.

## **RESULTS**

The participant recruitment process is summarized in Figure 1. About two thirds (3839/5791) of the pharmacy customers purchasing an OTC analgesic bought the product for headache. Among the 2042 individuals who matched the inclusion criteria, 837 (41.0%) refused to participate in the study for several reasons: no time (348/837; 41.6%), no interest (306/837; 36.6%), deprivation of privacy (69/837; 8.2%), and other reasons (114/837; 13.6%).

Overall, 1205 individuals agreed to participate in the survey: 983 (81.6%) were women and 222 (18.4%) were men. The mean age of the study population was 46.3 years (range 18-88). Seventy-nine (6.6%) of the respondents were aged under 25 years, 351 (29.1%) were between 25 and 40 years, 482 (40.0%) were between 41 and 55 years, 207 (17.2%) were between 56 and 70 years, and 86 (7.1%) were aged over 70 years.

### **Headache characteristics**

Fifty-six % of the participants (n=677) reported a physician diagnosis of headache, mainly migraine and tension-type headache (TTH) (Table 1). Seventy-eight % of them (530/677) scored positive on the ID-M, the physician diagnoses of these individuals were: migraine (n=383), TTH (n=101), patient failed to remember diagnosis (n=36), cluster headache (n=7), MOH (n=2) and headache as side effect of oral progesterone use (n=1). Forty-four % of the study population (n=528) did not have a physician diagnosis of their headache, and 225 of them (225/528, 42.6%) were found to be ID-M positive.

Almost 60% of participants reported a MIDAS score  $\leq 10$ , indicating no to mildly limiting disability (grade I-II) (Table 2). About 40% had MIDAS grade III (moderately limiting disability) or IV (severely limiting disability). The median headache pain severity was 6, with most patients rating pain between 5 and 8 on a 0-10 scale. Participants reported a median of 12 headache days in the last 3 months (Table 2).

### **Medication use**

The median number of acute headache drugs per patient was 2 (range 1-6). About one fifth of participants consumed 3 or more different acute headache treatments. About 73% (881/1205) only used OTC medication, and 27% used OTC as well as prescription drugs. The most commonly used acute medications are shown in Table 3. One-quarter of the patients physician-diagnosed with migraine currently used triptans (106/426), and about 12% used prophylactic migraine medication (49/426): propranolol (n=21), topiramate (n=16), amitriptyline (n=4), flunarizine (n=4), bisoprolol (n=4), riboflavin (n=3), valproate (n=2), pizotifen (n=1), losartan (n=1) and oxeterone (n=1). The

triptan and prophylaxis use by migraine patients, as a function of MIDAS grade, are displayed in Figure 2.

Only 14.5% was ever advised to limit intake frequency of acute headache treatments. About one quarter of our sample (n=292, 24.2%) chronically overused acute medication, which was combination analgesic overuse (n=166), simple analgesic overuse (n=130), triptan overuse (n=19), ergot overuse (n=6) and opioid overuse (n=5).

### **Characterisation of medication overusers**

Three-quarters of the medication overusers (220/292) had a physician diagnosis of headache: migraine (123/220; 55.9%), TTH (68/220; 30.9%), MOH (4/220; 1.8%) and cluster headache (4/220; 1.8%). Some patients failed to remember the diagnosis (21/220; 9.5%). Of the 4 overusers with cluster headache, 2 were triptan overusers and 2 were simple analgesic and/or combination analgesic overusers. About 70% of the migraineurs (87/123) had moderate or severe migraine (MIDAS grade III or IV), and only 13 of them (14.9%) used preventive medication and 27 (31.0%) used triptans. Based on the ID-M, migraine was likely in a substantial number of TTH patients (42/68; 61.8%). Of the patients without physician diagnosis, almost half (35/72) was found to be ID-M positive.

With respect to drug consumption, medication overusers were more likely to use 3 or more different acute headache drugs than non-overusers (Table 4). There were significantly less users of paracetamol and NSAIDs, and significantly more users of codeine-containing combination analgesics, caffeine-containing combination analgesics, triptans, ergots and opioids among medication overusers than among non-overusers. Overusers also reported higher headache-related disability (i.e., MIDAS grade) ( $p<0.001$ ), more frequent headaches ( $p<0.001$ ) and higher pain intensity ( $p<0.001$ ), compared to non-overusers (Table 4). Remarkably, 39% of overusers had <30 days of headache in the past 3 months, but used acute headache drugs for  $\geq 10$  days/month (for triptans, ergots, opioids and combination analgesics) or  $\geq 15$  days/month (for simple analgesics).



## DISCUSSION

This observational survey provides information about the characteristics and the medication consumption of pharmacy customers seeking self-medication for regular headache (defined for this study as headache occurring at least once per month). Headache showed to be an important reason for OTC analgesic purchase, as two thirds of the dispensed OTC analgesics were used to treat headache. Our study identified three main problems with headache management: (i) migraine is underdiagnosed, (ii) patients with a physician diagnosis of migraine may receive suboptimal treatment, and (iii) the prevalence of medication overuse is high.

Almost half of individuals without physician diagnosis of migraine scored positive on the ID-M. As the ID-M is a screening instrument with high positive predictive value (8), we can assume that the majority of them will indeed suffer from migraine. This is in line with previous research, showing that migraine is underdiagnosed in primary care (12-14). Most of our participants with possible migraine did not have a physician diagnosis (suggesting that persons with migraine complaints either do not consult a physician or do consult a physician but do not receive a diagnosis) or were wrongly diagnosed as having TTH. Such underrecognition of migraine might prompt inappropriate self-medication practices. Indeed, about one quarter of the possibly undiagnosed migraine patients in our study met the ICHD-IIIR criteria of medication overuse. Concerning the ID-M, it is noteworthy that its sensitivity is 81%, thus not all participants with a physician diagnosis of migraine scored ID-M positive. Its specificity is 75% which led to cluster headache patients scoring positive (8).

Only 12% of the physician-diagnosed migraine patients in this study was prescribed preventive medication. This percentage is similar to that found in previous studies conducted in the U.S. (12%) (15), Italy (14%) (16), The Netherlands (8%) (17), and France (6%) (18). Migraine prophylaxis is indicated for patients with frequent disabling attacks (19), and it has been proven effective in reducing resource utilization (20) and in improving quality of life and activity limitations (21). Nevertheless, only 8% of the MIDAS grade III migraine patients in this study and only 17% of the MIDAS grade IV migraine patients were prescribed preventive therapy. It should be noted, however,

that this study only looked at current use of prophylaxis. Patients may already have used prophylaxis in the past but terminated treatment due to adverse effects, insufficient therapeutic effect or other reasons. Another finding indicating possible suboptimal migraine treatment is the fact that only one quarter of the migraineurs with MIDAS III-IV used triptans. Triptans may have significant effects on quality of life of migraine patients and on migraine-related costs (22-26). The low use of triptans in this study could be related to the stepped-care approach used in Belgium, whereby migraine-specific therapy may be delayed far more than in stratified care. In addition, patients may not follow-up with their physician when the initial treatment step (e.g., simple analgesic) fails and instead they may lapse from medical care (27, 28). As mentioned above for prophylaxis use, it should be borne in mind that the non-triptan users in this study may have tried triptans in the past but stopped. It is also relevant to note that triptans are available only by prescription in Belgium, in contrast to the neighbouring countries UK and Germany where some are OTC available (29).

Another important finding is the high prevalence of medication overuse (24%). However, less than 1% of the study population had a physician diagnosis of MOH. Our data suggest that consumers of three or more different acute headache drugs are more likely to overuse. A substantial proportion of overusers did not have chronic headache, meaning that they also used the analgesics for other pain conditions than headache (unfortunately, we did not record for what other conditions). However, these patients are also at risk for developing MOH, due to their regular headache in combination with medication overuse. We also found that patient education about limits on the use of analgesics is poorly implemented in Belgian practice, as only 15% ever received such advice.

Based on the results of this study, recommendations for improved community pharmacy management of headache complaints can be formulated. Firstly, pharmacists are in a unique position to improve migraine recognition in primary care. Pharmacy customers seeking self-medication for regular headache could be asked to complete the ID-M, and if positive, referral to a general practitioner should be made. In this way, the number of headache patients seeking medical care could be increased, as lack of consultation is a major contributing factor to the underdiagnosis of

migraine (30). From a practical point of view, the ID-M showed to be an easy to use method for migraine screening in the community pharmacy setting. Secondly, pharmacists could play an important role in prevention and early detection of medication overuse and subsequent MOH. The most important preventive measure is proper instruction and appropriate surveillance of patients (31). Patients may often be unaware of the risk of the developing rebound headache when frequently using analgesics. Therefore, simple pharmacist advice regarding the maximum intake frequency (routinely provided at dispensation of acute headache medication) seems useful. Provided that they keep records of OTC medication dispensing, pharmacists are also well-placed to alertly follow up individuals regularly purchasing OTC products for headaches. At suspicion of medication overuse, patients should be informed about the possible link between their chronic headache and their medication use, and encouraged to consult a physician. Previous studies conducted in the hospital setting have proven that simple advice is effective in both prevention and treatment of MOH (32, 33). Thirdly, migraine patients with frequent disabling attacks who are not experiencing sufficient pain relief with their current treatment should be referred to a physician for other therapeutic options (triptans and/or preventive treatment; available by prescription only in Belgium). This study has some limitations. Physician diagnosis and medication use were based on self-reporting, which holds the risk of recall bias. Another limitation is that this study only screened for medication overuse, but did not make MOH diagnosis. Finally, the Dutch versions of the ID-M and the MIDAS have not been formally validated. However, previous validation studies on translations of both instruments did not report problems (34-37). The main strength is that this is the first extensive survey providing data on the headache complaints and drug utilization of self-medicating individuals in the community pharmacy setting. Furthermore, our study design and setting aimed to minimize the risk of selection bias: (i) the community pharmacies participating in this study were randomly selected, and each of them recruited a similar number of participants, (ii) pharmacy customers were randomly recruited (i.e., consecutively), and (iii) in Belgium, the sale of OTC medicines is limited to

pharmacies, meaning that we sampled from the entire population of persons with self-medication intentions.

In conclusion, this study identified underdiagnosis of migraine, low use of migraine prophylaxis and triptans, and underdiagnosis of MOH among subjects seeking self-medication for regular headache. Community pharmacists have a strategic position in education and referral of these self-medicating headache patients.

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## CONFLICTS OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

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## TABLES AND FIGURES: captions

Table 1: Physician diagnosis of headache.

Table 2: Headache-related disability, frequency of headaches and pain intensity (based on the MIDAS questionnaire).

Table 3: Acute headache medication used by the study population.

Table 4: Acute headache medication use and headache-related disability, frequency of headaches and pain intensity of medication overusers vs non-overusers.

Figure 1: Flow scheme of the participant recruitment process.

Figure 2: Prophylaxis and triptan use by patients with a physician diagnosis of migraine, as a function of MIDAS grade.